SEP 13 2012

510 (K) Summary (21 CFR 807.92)

510(K) Summary

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of SMDA 1990 and 21 CFR 807.92.

The assigned 510(K) number is: K112741 (applicant leave blank)

Premarket Notification [510(K)] Summary

[(a)(1)] The summary contains on the first page, preferably on your letterhead paper, the submitter's name, address, phone and fax numbers, name of contact person, and date the summary was prepared:

Submitter's name:	Lifestyle Safety Products (Hui Zhou) Co., Ltd
Submitter's address:	Daxiaotang Village, Luoyang Town, Boluo County Hui Zhou City, Guang Dong Province, 516120 China
Phone Number:	0086-0752-6865040
Fax Number:	0086-0752-6863392
Name of contact person:	Ms. Yew Sing Mei
Date the summary was prepared:	January 26, 2011

[(a)(2)] The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known

Device/ Proprietary Name: (Non-Sterile)	Powder Free Vinyl Patient Examination Gloves,
Common Name:	Patient examination glove
Classification Name:	Patient examination glove
Device Classification:	I
Regulation Number:	21 CFR 880.6250
Panel:	General Hospital
Product code:	LYZ

[(a)(3)] An identification of the legally marketed device to which your firm is claiming substantial equivalence.

Predicate Device Information:
(1) K100978, "Powder-Free Non-Sterile Vinyl Examination Glove", manufactured by "Jiangsu Sunshine Plastic Products, Co., Ltd"

[(a)(4)] A description of the device

Device Description: Powder Free Vinyl Patient Examination Gloves (Non-Sterile), that meets all of the requirement of ASTM standard D 5250-06e1, except for sterility requirements.

[(a)(5)] The summary describes the intended use of the device

Device Intended Use: Powder Free Vinyl Patient Examination Gloves (Non-Sterile) is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. It is sold as non sterile.

Comparison to Predicate Devices

The Powder free Vinyl patient examination gloves (Non-Sterile) are compared with the following Predicate Devices in terms of intended use, design, material, specification, and performance.

(1) K100978, "Powder-Free Non-Sterile Vinyl Examination Glove", manufactured by "Jiangsu Sunshine Plastic Products, Co., Ltd"

(2)

The following table shows similarities and differences of use, design, and material between our device and the predicate devices.

Table 5.1 Comparison of Intended Use, Design, and Material

Description	Our Device	Predicate Device (K100978)
Indication for Use	Disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner	Same
Basic Design Material	Poly Vinyl Chloride	Same
Size	S, M, L, XL	Same
Single Use	Yes	Yes
Sterile	Non sterile	Non sterile

[(a)(6)] A summary of the technological characteristics of new device compared to the predicate device

The Powder Free Vinyl Patient Examination Gloves (Non-Sterile) are summarized with the following technological characteristics compared to ASTM or equivalent standard.

Characteristics	Our device	Predicate Device Performance
Dimension	Meets ASTM D 5250-06e1	Meets ASTM D 5250-06e1
Physical Properties	Meets ASTM D 5250-06e1	Meets ASTM D 5250-06e1
Freedom from pinholes	Meets ASTM D5151-06	Meets 21 CFR 800.20
Powder Residual	Meets ASTM D5250-06e1 and D6124-01	Meets ASTM D6124-01
Biocompatibility	Primary Dermal Irritation in rabbits Dermal Sensitization in the guinea pig	Passes Passes

[(b)(1)] A brief discussion of the nonclinical submitted, reference, or relied on in the premarket notification submission for a determination of substantial equivalence.

Powder Free Vinyl Patient Examination Gloves (Non-Sterile), meet the requirements per ASTM D5250-06e1, per ASTM D6124-01, and ASTM 5151-06. It is safe and effective, and its performance meets the requirements of its pre-defined acceptance criteria and intended uses.

[(b)(2)] A brief discussion of the clinical submitted, reference, or replied on in the premarket notification submission for a determination of substantial equivalence.

Clinical data is not needed for gloves or for most devices cleared by the 510(K) process.

[(b)(3)] The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performed as well or better than legally marketed device identified in (a)(3).

Based on the comparison of intended use, design, materials, and performance, it can be concluded that our vinyl disposable examination gloves powder free non-sterile, meets the ASTM standard or equivalent standard and FDA requirements for water leak test on pinhole AQL., meet labeling claims and are substantial equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 13 2012

Lifestyle Safety Products (Hui Zhou) Company, Limited
C/O Registrar Corporation
Ms. Rhonda T. Alexander
Senior Regulatory Specialist
Medical Device & Drug Division
144 Research Drive
Hampton, Virginia 23666

Re: K112741
Trade/Device Name: Powder-Free Vinyl Patient Examination Gloves (Non-Sterile)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYZ
Dated: September 4, 2012
Received: September 5, 2012

Dear Ms. Alexander:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Applicant: Lifestyle Safety Products (Hui Zhou) Co., Ltd

510(k) Number (if known): N/A K112741

Device Name: Powder Free Vinyl Patient Examination Gloves (Non-Sterile)

Indications for Use:

The powder free vinyl patient examination glove (non-sterile) is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. It is sold as non sterile.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

9/12/12

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K112741